

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

PFIZER INC., WYETH LLC, WYETH	)	
PHARMACEUTICALS INC., and PF PRISM	)	
C.V.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. _____
	)	
MYLAN PHARMACEUTICALS INC. and	)	
MYLAN INC.,	)	
	)	
Defendants.	)	

**COMPLAINT**

Plaintiffs Pfizer Inc., Wyeth LLC, Wyeth Pharmaceuticals Inc., and PF Prism C.V. (collectively “Plaintiffs”), by their undersigned attorneys, for their Complaint against Defendants Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively “Mylan”) herein allege:

**NATURE OF THE ACTION**

1. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, arising from Mylan’s filing of an Abbreviated New Drug Application (“ANDA”) with the United States Food and Drug Administration (“FDA”) seeking approval to market a generic version of Pfizer’s pharmaceutical product Pristiq® prior to the expiration of United States Patent No. 6,673,838 (“the ‘838 patent”) which covers Pristiq® and its uses.

**THE PARTIES**

2. Plaintiff Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 235 East 42nd Street, New York, New York.

3. Plaintiff Wyeth LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a place of business at 5 Giralta Farms, Madison, NJ 07940. Pfizer Inc. is the ultimate parent of Wyeth LLC.

4. Plaintiff Wyeth Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 500 Arcola Road, Collegeville, PA 19426. Pfizer Inc. is the ultimate parent of Wyeth Pharmaceuticals Inc.

5. Plaintiff PF Prism C.V. is a Netherlands limited partnership (commanditaire vennootschap) having its registered seat in Rotterdam, the Netherlands, and registered at the Trade Register held by the Chamber of Commerce of Rotterdam, the Netherlands, under number 51840456, with main offices at Blaak 40 basement, 3011 TA, Rotterdam, Netherlands. Pfizer Inc. is the ultimate parent of PF Prism C.V.

6. On information and belief, Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of West Virginia, having a principal place of business at 781 Chestnut Ridge Rd., Morgantown, West Virginia 26505. On information and belief, Mylan Pharmaceuticals Inc. is registered to distribute drugs in the State of Delaware, and is in the business of making and selling generic pharmaceutical products, which it distributes in the State of Delaware and throughout the United States. On information and belief, Mylan Pharmaceuticals Inc. holds an active pharmacy wholesaler license in Delaware, is registered to do business in Delaware, and has designated an agent for the service of process in Delaware. On information and belief, Mylan Pharmaceuticals Inc. is a wholly owned subsidiary of Mylan Inc. Mylan Pharmaceuticals Inc. has previously submitted to jurisdiction in this Court, and has purposefully availed itself of the jurisdiction of this Court by filing lawsuits and by asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware.

7. On information and belief, Mylan Inc. is a corporation organized and existing under the laws of the State of Pennsylvania, having a principal place of business at 1500 Corporate Drive, Canonsburg, PA 15317. On information and belief, Mylan Pharmaceuticals Inc., with the assistance and/or direction of Mylan Inc. develops, manufactures, markets, offers to sell, and sells generic drug products for sale and use throughout the United States. Mylan Inc. has previously submitted to jurisdiction in this Court, and has purposefully availed itself of the jurisdiction of this Court by filing lawsuits and by asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware.

**JURISDICTION AND VENUE**

8. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. This Court has personal jurisdiction over Mylan by virtue of, *inter alia*, its presence in Delaware, having conducted business in Delaware, having availed itself of the rights and benefits of Delaware law, previously consenting to personal jurisdiction in this Court, availing itself of the jurisdiction of this Court, and having engaged in systematic and continuous contacts with the State of Delaware.

10. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

**THE PATENT-IN-SUIT**

11. On January 6, 2004, the United States Patent and Trademark Office issued the '838 patent, entitled "Succinate Salt of O-Desmethyl-Venlafaxine." At the time of its issue, the '838 patent was assigned to Wyeth (now known as Wyeth LLC), Madison NJ, and Wyeth

LLC currently holds title to the '838 patent. A copy of the '838 patent is attached hereto as Exhibit A.

**PRISTIQ®**

12. Pfizer Inc., itself and through its wholly owned indirect subsidiary Wyeth Pharmaceuticals, Inc., holds approved New Drug Application No. 21-992 ("the Pristiq® NDA") for O-desmethylvenlafaxine succinate extended release tablets in 50 and 100 mg dosage strengths, which are sold by Pfizer Inc. under the trade name Pristiq®.

13. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '838 patent is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Pristiq®.

**MYLAN'S ANDA**

14. On information and belief, Mylan submitted ANDA No. 20-4095 (the "Mylan ANDA") to the FDA, pursuant to 21 U.S.C. §§ 355(j), seeking approval to market O-desmethylvenlafaxine succinate extended release tablets in 50 and 100 mg dosage strengths. The O-desmethylvenlafaxine succinate extended release tablets described in the Mylan ANDA are herein referred to as the "Mylan Products."

15. The O-desmethylvenlafaxine succinate described in the Mylan ANDA are herein referred to as the "Mylan Products."

16. The Mylan ANDA refers to and relies upon the Pristiq® NDA and contains data that, according to Mylan, demonstrate the bioequivalence of the Mylan Products and Pristiq®.

17. Pfizer received from Mylan a letter, dated May 29, 2012, and attached memoranda (collectively, the "Mylan Notification"), stating that Mylan had included a

certification in the Mylan ANDA, pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the ‘838 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of the Mylan Products (“the Paragraph IV Certification”).

**COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 6,673,838**

18. Pfizer realleges and incorporates by reference the allegations of paragraphs 1-16 of this Complaint.

19. Mylan has infringed the ‘838 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Mylan ANDA, by which Mylan seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Mylan Products prior to the expiration of the ‘838 patent.

20. Mylan’s commercial manufacture, use, offer to sell, or sale of the Mylan Products within the United States, or importation of the Mylan Products into the United States during the term of the ‘838 patent would further infringe the ‘838 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

21. Pfizer will be substantially and irreparably harmed if Mylan is not enjoined from infringing the ‘838 patent.

22. Pfizer has no adequate remedy at law.

23. This case is an exceptional one, and Pfizer is entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

**PRAYER FOR RELIEF**

WHEREFORE, Pfizer Inc., Inc., Wyeth LLC, Wyeth Pharmaceuticals Inc. and PF Prism C.V. pray for a judgment in its favor and against Defendants Mylan Pharmaceuticals Inc. and Mylan Inc., and respectfully request the following relief:

- A. A judgment declaring that Mylan has infringed U.S. Patent No. 6,673,838;
- B. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Mylan, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from manufacturing, using, offering to sell, or selling the Mylan Products within the United States, or importing the Mylan Products into the United States, prior to the expiration date of the '838 patent;
- C. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 20-4095 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the expiration date of the '838 patent, including any extensions;
- D. If Mylan commercially manufactures, uses, offers to sell, or sells the Mylan Products within the United States, or imports the Mylan Products into the United States, prior to the expiration of the '838 patent, including any extensions, a judgment awarding Pfizer monetary relief together with interest;
- E. Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;
- F. Costs and expenses in this action; and
- G. Such other relief as the Court deems just and proper.

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